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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,005	03/11/2004	James Rasmussen	PEPT-P01-005	7191
28120	7590	04/01/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			SZPERKA, MICHAEL EDWARD	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 04/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,005

Applicant(s)

RASMUSSEN ET AL.

Examiner

Michael Szperka

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

H/C

DETAILED ACTION

1. Claims 1, 4, and 11 have been amended.
Claims 12 and 13 have been added.
Claims 1-13 are currently pending in this application.

Response to Arguments

2. The submission of a substitute specification by Applicant to correct minor errors is acknowledged.
3. Applicant's response received Feb. 3, 2005, indicates that a new declaration has been submitted to address the issue of a handwritten alteration that is not initialed and dated, and that therefore the objection should be removed. Currently there does not appear to be any oath or declaration in this application other than the defective declaration filed on July 6, 2004. As such, the objection is maintained and a new oath or declaration is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 1-11 for failing to have adequate written description in the specification as filed has been obviated by Applicant's amendment to base claim 1. As such, the rejection has been removed.

6. Claims 1-11 stand rejected and newly presented claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

These claims are rejected for the reasons of record set forth in section 4 of the Office action mailed November 3, 2004. Applicant has argued in the response received February 3, 2005, that the specification provides sufficient detail for a skilled artisan to make and use the polypeptides and compositions currently recited. These arguments have been considered, but have not been found convincing.

The examiner agrees with Applicant that the specification provides sufficient enablement to make the peptides and compositions of claims as currently recited. However, the specification does not provide sufficient enablement for how to use the peptides and compositions of the instant claims. On page 6 of Applicant's reply received February 3, 2005, it is argued that the specification provides 3 separate uses for the claimed peptides and compositions. All three of these uses occur *in vivo*, and have the common theme that recognition of the claimed desmoglein 3 peptide

Art Unit: 1644

sequence (SEQ ID NO:1) by cells of the immune system causes or lessens the severity (through the process of tolerance) of the autoimmune disease pemphigus vulgaris (PV). Since all of the disclosed uses are *in vivo*, inquiry into the *in vivo* efficacy of SEQ ID NO:1 is relevant to the enablement of the pending claims. As stated in the Office action mailed November 3, 2004, Veldman et al. (of record) demonstrate T cell recognition of an epitope corresponding to SEQ ID NO:1 in PV patients and in healthy controls, indicating that recognition of this epitope is not causative or therapeutic for PV.

Applicant's disclosure does not provide data or working examples of the disclosed uses for the peptide of SEQ ID NO:1. Based on the teachings of Veldman et al., a skilled artisan would not know how to use the peptide of SEQ ID NO:1 in Applicant's disclosed embodiments for the use of SEQ ID NO:1 since these embodiments require that SEQ ID NO:1 be a causative or therapeutic agent for PV, yet Veldman et al. specifically state at the end of their abstract that recognition of distinct desmoglein 3 peptides (one of which is essentially equivalent to SEQ ID NO:1) by T cells is independent from the development of PV. As such, a skilled artisan would need to conduct further research to determine how to use the peptide of SEQ ID NO:1 since the uses disclosed by Applicant are contradicted by the teachings of Veldman et al.

7. No claims are allowable

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
March 24, 2005


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600